Remarks

Claims 5, 10, and 15-16 are currently pending in the present application. Applicants would like to acknowledge the Examiner's entry of the amendment filed on February 23, 2007, and subsequent withdrawal of the previous final Office Action.

Previously Allowable Subject Matter

In the previous Office Action, dated October 18, 2006, the Examiner indicated that claim 15 was "free of the prior art" but was objected as dependent from a rejected independent claim. Applicants subsequently amended claim 15 to be in independent form, including all limitations of now-canceled claim 8. Claims 5, 10, and 16 were amended to be dependent on allowable independent claim 15. In that previous Office Action, the Examiner stated that "Chatzistamou et al. and/or Trouet et al, do not teach or suggest, alone or in combination, a drug delivery complex for treating cancer comprising a complex conjugate of the following components: an anticancer agent; a poly(ethylene glycol) polymer; a BH3 peptide; and lutienizing hormone-releasing hormone (LHRH)." Therefore, the Examiner stated that claim 15 would be allowable.

However, in the present Office Action, the Examiner has rejected claim 15, and those claims dependent thereon, as allegedly obvious under 35 U.S.C. § 103(a) over Trouet (WO 01/91798) in view of Chatzistamou (Clinical Cancer Research 2000; 6:4158-4165). Notably, these are the very two references that claim 15 was deemed to be allowable over. Applicant respectfully submits that the Examiner's statement in the previous final Office Action is correct, and the present claims are not obvious over the cited references.

Claim Rejection

As stated above, the Examiner has rejected claims 5, 10, and 15-16 as allegedly obvious over Trouet in view of Chatzistamou. Applicant respectfully traverses this rejection, and submits that the claims as pending are allowable over the cited references.

Independent claim 15 requires a complex drug delivery composition for treating cancer comprising a complex conjugate of (a) an anticancer agent; (b) a poly(ethylene glycol) polymer; LHRH; and a BH3 peptide. The claims dependent on claim 15 further require that the components of claim 15 be operably-linked by a scaffold, and further that the scaffold be a peptide. Dependent claim 5 is directed to a method of producing a complex drug delivery composition by combining a scaffold with the composition of claim 15.

Trouet is directed to a prodrug compound for inhibition of the growth of tumors. Trouet discloses as its novel prodrug a compound requiring three specific components: a masking moiety, a linking moiety, and a biologically active entity. The biologically active entity may include anticancer agents, as well as BH3 peptides. Trouet additionally discloses that the masking moiety may include poly(ethylene glycols).

Trouet's disclosure emphasizes the novelty and importance of its "linking moiety". The linking moiety is defined as a molecular moiety that "links a biologically active entity to a masking moiety and that is susceptible to specific, selective cleavage at or near a tumor or target cell." (page 9, lines 16-18). The disclosure states that tumors and target cells secrete a factor or factors (such as proteases or peptidases) "that are capable of specifically cleaving the linking moiety." (page 10, lines 33-35). According to Trouet's disclosure, when the prodrug compound is in the presence of such target cell factors, the linking moiety is cleaved, separating the masking moiety and the biologically active entity. Once freed from the masking moiety, the biologically active entity exerts its activity on the target cell. (page 11, lines 8-33).

Thus, Trouet's prodrug compound is based upon and requires use of the linking moiety. The linking moiety is critical in that the compound stays masked and inactive until it is in the presence of the released target cell secretion(s), at which point the biologically active entity is freed and allowed to act. The linking moiety controls the selectivity of the compound.

Chatzistamou discloses the use of LHRH linked to doxorubicin to form a cytotoxid analogue, which is targeted to LHRH receptors. Chatzistamou is silent as to the use of poly(ethylene glycol) in combination with both an anticancer agent as well as BH3 peptide.

In the instant office action, the Examiner has asserted that it would have been obvious to one ordinary skill in the art at the time the invention was made to combine the teachings of these references so as to modify the prodrug taught by Trouet et al. to include LHRH, in view of the teachings of Chatzistamou et al. The Examiner also asserts that one of ordinary skill in the art would have a reasonable expectation of success that, by modifying the prodrug by Trouet et al. to include LHRH in view of the teachings of Chatzistamou et al., one would achieve a drug delivery complex which targets tumors having LHRH receptors and treating these tumors.

Applicants respectfully traverse this rejection. First and foremost, Chatzistamou and Trouet do not teach, alone or in combination, a drug delivery complex for treating cancer comprising a complex conjugate of the components presently claimed. As such, claim 15 is not obvious over the cited references, and should be allowed.

One following the teachings of Trouet would not be motivated to incorporate Chatzistamou's LHRH, in view of the required linking moiety of Trouet. There would be no "apparent reason" to include LHRH into the compound of Trouet, given the selectivity of the linking moiety. As explained at length in Trouet, the allegedly novel feature of Trouet is the inclusion of the linking moiety, which allows the biologically active agent to stay inert until it is cleaved from the masking moiety, which will only occur in the presence of a selected tumor or

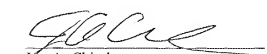
target cell. The linking moiety thus provides the necessary selectivity for the compound, allowing the biologically active agent to act only in select circumstances. Addition of an LHRH carrier would be duplicative and unnecessary in light of the linking moiety. The linking moiety already provides the selectivity desired, and there would be no apparent reason to add the LHRH carrier. As such, one skilled in the art would have no reason or motivation to add a LHRH carrier to the disclosure of Trouet. As such, claim 15 is not obvious over the cited references, and is in position for allowance.

Further, even if one was to consider combining the compound of Trouet with the LHRH of Chatzistamou, one skilled in the art would realize that there would likely be an issue of steric hindrance between the components, rendering the combination impractical. Such steric hindrance would be likely to decrease the activity of each component and thus each component's effectiveness. Thus, one skilled in the art would avoid combining the teachings of Trouet with Chatzistamou.

Summary

Applicants submit that the claims as submitted are patentably distinct over the art and allowable in form, and an allowance of the claims is respectfully solicited. Should the Examiner have any questions regarding this response, the Examiner is encouraged to contact the undersigned at the telephone number set forth below.

Respectfully submitted,



Jon A. Chiodo
Registration No.: 52,739
Agent for Applicants

HOFFMANN & BARON, LLP
6900 Jericho Turnpike
Syosset, New York 11791
(973) 331-1700